

REMARKS/ARGUMENTS

Claims 1, 4-8, 11, 15-18, 21-26, 29, 36, 38-43 and 46-48 were pending in the present case and were under examination. With entry of the present Amendment, claims 1, 18, 35 and 39 have been amended, and claims 6, 23 and 40 have been canceled without prejudice to further prosecution. Support for the amendments made to the claims can be found in the specification and claims as originally filed and, thus, no new matter is introduced. Reconsideration is respectfully requested in view of the amendments to the claims and the following remarks.

Claims 1, 4-8, 11, 15-18, 21-26, 29, 36, 38-43 and 46-48 were objected to and/or were rejected, in various combinations, under 35 U.S.C. § 112, first and second paragraphs, and under 35 U.S.C. § 103. For the reasons set forth herein, each of these rejections is overcome.

Objection to the Claims

Claims 5, 6, 22, 23, 39 and 40 were objected to under 35 C.F.R. § 1.75(c), as “being of improper dependent form for failing to further limit the subject matter of a previous claim” (*see*, page 2 of the Office Action).

As pointed out in the Office Action, each of claims 4, 21 and 38 recite that “the detectable molecular probe is not labeled with a detectable moiety.” As set forth in the specification, the detectable molecular probe can be “directly” or “indirectly” detected, and claims 4, 21 and 38 are directed to the embodiment, wherein the detectable molecular probe is indirectly detected. As recited in claims 5, 22 and 39, the detectable molecular probe can be “indirectly” detected by using, for example, an antibody (that itself can be detected) which specifically binds to a complex of the detectable molecular probe and the target sequence of the microbial organism of interest. As such, claims 5, 22 and 39 do, in fact, further limit the scope of claims 4, 22 and 38, respectively.

Applicants have reviewed claims 6, 23 and 40 and, in view of the amendments previously made to the independent claims from which they ultimately depend (*i.e.*, claims 1, 18 and 35), Applicants have canceled these claims without prejudice to further prosecution.

In view of the foregoing, Applicants respectfully submit that claims 5, 22 and 39 do, in fact, further limit the claims from which they depend. Accordingly, Applicants urge the Examiner to withdraw this objection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 4-8, 11, 15-18, 21-26, 29-31 and 35 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner's concern and, in turn, Applicants' responses to those concerns are set forth below.

The test for indefiniteness is “whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity” (MPEP § 2173.02). This analysis does not occur in a vacuum, but rather in view of the following factors: (1) the content of the particular application disclosure; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. In addition, “the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope” (MPEP § 2173.02).

a. The Examiner has objected to the preamble of claim 1, stating that it seems redundant in that “one is determining the presence of a microbe and also distinguishing it from other organisms” (*see*, page 3 of the Office Action.).

In order to expedite prosecution, Applicants have amended claim 1 to delete the phrase “to be distinguished.” As amended, claim 1 recites “[a] method for determining the presence of a microbial organism of interest in a sample from another organism or organisms.”

In view of the amendment to claim 1, which are formalistic in nature, the Examiner's concern is rendered moot. Accordingly, Applicants urge the Examiner to withdraw this portion of the rejection under 35 U.S.C. § 112, second paragraph.

b. The Examiner has objected to claim 18, stating that although there is proper antecedent basis for the phrase “detectable or independently detectable molecular probes,” there does not appear to be proper antecedent basis for the phrase “the detectable or independently

detectable organisms,” or for the phrase “the presence, absence or number of detectable microbial organisms.”

In order to expedite prosecution, Applicants have amended the preamble of claim 18 to more specifically recite “[a] method for determining the presence, absence or number of a microbial organism or microbial organisms of interest in a sample or samples,” thereby providing proper antecedent support for the phrase “the presence, absence or number of detectable microbial organisms.” In addition, claim 18 has been amended so that the phrases “different detectable microbial organisms” or “different independently detectable microbial organisms” are consistently used.

In view of the amendments to claim 18, which are formalistic in nature, the Examiner’s concern is rendered moot. Accordingly, Applicants urge the Examiner to withdraw this portion of the rejection under 35 U.S.C. § 112, second paragraph.

c. The Examiner has objected to claim 35, stating that although there is proper antecedent basis for the phrase “detectable or independently detectable molecular probes,” there does not appear to be proper antecedent basis for the phrase “the detectable or independently detectable organisms,” or for the phrase “the presence, absence or number of detectable microbial organisms.”

In order to expedite prosecution, Applicants have amended the preamble of claim 35 to more specifically recite “[a] method for determining the presence, absence or number of different microbial organisms of interest in a sample or samples,” thereby providing proper antecedent support for the phrase “the presence, absence or number of detectable microbial organisms.” In addition, claim 35 has been amended so that the phrases “different detectable microbial organisms” or “different independently detectable microbial organisms” are consistently used.

In view of the amendments to claim 35, which are formalistic in nature, the Examiner’s concern is rendered moot. Accordingly, Applicants urge the Examiner to withdraw this portion of the rejection under 35 U.S.C. § 112, second paragraph.

d. The Examiner has objected to claim 35, stating that there is insufficient antecedent basis for the phrase "the same stain."

In order to expedite prosecution, Applicants have amended claim 35 to recite "a same stain." In view of this amendment to claim 35, which is stylistic in nature, the Examiner's concern is rendered moot. Accordingly, Applicants urge the Examiner to withdraw this portion of the rejection under 35 U.S.C. § 112, second paragraph.

e. The Examiner has objected to claims 4-6, 21-23 and 38-40, stating that it is unclear "what constitutes the metes and bounds of 'detectable molecular probe.'"

As taught in the specification, all of the molecular probes are "detectable," but they can be directly detected or indirectly detected. If directly detected, the molecular probe is labeled with a detectable moiety (*e.g.*, a chromophore, a fluorochrome, *etc.*). However, if indirectly detected, the molecular probe is not labeled with a detectable moiety, but instead is detected by other means. For instance, the complex formed between the molecular probe and the target sequence of the microbial organism of interest can be detected using an antibody raised to bind to the probe/target sequence complex (*see*, the specification at page 13, lines 9-20, entitled "Unlabeled Molecular Probes"). Thus, the specification makes it clear that even an "unlabeled" probe can be detected.

As explained above in connection with the "Objection to the Claims," claims 4, 21 and 38 are directed to the embodiment wherein the "detectable molecular probe" is "indirectly" detected. As recited in claims 5, 22 and 39, the detectable molecular probe can be "indirectly" detected by using, for example, an antibody (that can itself be detected) which specifically binds to a complex of the detectable molecular probe and the target sequence of the microbial organism of interest.

In view of the teachings provided in the specification, the use of the term "detectable molecular probe" in the claims is clear and, thus, the Examiner's concern is unfounded. Accordingly, Applicants urge the Examiner to withdraw this portion of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 103

Claims 1, 4-8, 11, 15-18, 21-26, 29-31, 34, 38-43 and 46-48 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,110,676 (Coull *et al.*) in view of U.S. Patent No. 5,612,458 (Hyldig-Nielsen *et al.*) and U.S. Patent No. 5,225,584 (Brooks *et al.*). To the extent that the rejection applies to the amended claims, Applicants respectfully traverse this rejection.

A claim is considered obvious “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains” (35 USC § 103(a)). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper “functional approach” to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. One of the rationales addressed by the court in *KSR* supports a finding of obviousness when the prior art reference (or combination of references) (1) teaches or suggests the claim elements; (2) provides some suggestion or motivation to combine the references; and (3) provides a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2143.

Although various elements of the claimed invention can be found in the numerous cited references, Applicants respectfully submit that Coull *et al.*, Hyldig-Nielsen *et al.* and Brooks *et al.*, either alone or in combination, do **not** teach or suggest a method employing the selectivity and discriminating power of an antibody immobilized on a solid carrier (*e.g.*, a coded bead), as used in a capture assay, in combination with the selectivity and discriminating power of a PNA molecular probe, as used to stain microbial organisms, to provide for two independent levels of certainty and/or discrimination. Moreover, these cited references, either alone or in combination, does not teach or suggest a significant advantage of the presently claimed methods over the methods of the prior art. As set forth in the specification, one of the advantages of the

presently claimed methods is that the use of PNA probes (*i.e.*, molecular probes that are peptide nucleic acids) allows for the harmonization of the hybridization and antibody binding conditions because PNA probes bind more tightly under conditions of physiological salt, conditions under which antibodies are more likely to operate most efficiently.

In view of the foregoing, Applicants respectfully submit that the prior art of record (*i.e.*, Coull *et al.*, Hyldig-Nielsen *et al.* and Brooks *et al.*) does not teach or suggest the presently claimed methods or the advantages associated with such methods. Absent such teachings or suggestions in the prior art, the claimed invention is non-obvious and, thus, patentable. Accordingly, Applicants urge the Examiner to withdraw the rejection under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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